

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

1713 -AF ERW

In re Application of)
ANGEL et al.	Group Art Unit: 1713
Serial No. 09/964,796) Examiner: REDDICK, N
Filed: September 28, 2001)

For: WATER-SOLUBLE OF WATER-DISPERSIBLE (CO)POLYMERS OF HYDROXYALKYL (METH)ACRYLATES, A PROCESS FOR THEIR PREPARATION, AND THEIR USE AS COATING AGENT, BINDER AND/OR FILM-FORMING EXCIPIENT IN PHARMACEUTICAL DOSAGE FORMS

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Agnature
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Honorable Commissioner of Patents

REQUEST FOR RECONSIDERATION UNDER 37 CFR 1.116

In response to the Office action of June 7, 2004 applicants request reconsideration in view of the following remarks.

Claims 1-8 stand rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative under 35 U.S.C. 103(a) as obvious over Dagmer et al. (US 5,354,803).

Applicants respectfully traverse this rejection.

The presently claimed invention relates to polymers which are obtained by radical polymerization of a vinyl monomer mixture in the presence of a polyvinyl alcohol, wherein the monomer mixture must have a content of a hydroxyalkyl (meth)acrylate which is at least equal to the other possible vinyl monomer, i.e. at least 50% by weight of such hydroxy alkyl acrylate. This is an essential feature of the claimed invention.

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Also, the polymers according to the present invention must be water-soluble or waterdispersible when used in pharmaceutical dosage form, because otherwise the dosage forms would not release the active ingredient.

Dragner et al. cites hydroxy alkyl acrylates as suitable monomers (column 2, lines 55-56) but does not mention the above-indicated limitation as the minimum amount of a hydroxyalkyl (meth)acrylate in the monomer mixture. According to the examples, methyl methacrylate and butyl acrylate are used as monomers. The resulting polymers are used as binders for nonwoven fabrics for roofing mats, filter media, fiberglass or insulation (column 4, lines 37-42). It is clear from the disclosed fields of application that the polymers of Dragner et al. are not intended to be watersoluble or water-dispersible. A water-soluble or water-dispersible roof mat, for example, would be particularly undesirable during a rain fall.

Furthermore, Dragner et al. contains no suggestion or motivation to use the specifically claimed amount of hydroxyalkyl (meth)acrylate or that use of such an amount of hydroxyalkyl (meth)acrylate would render water-soluble or water-dispersible polymers. Also, the technical field of Dragner et al., which relates to surfactantless non-formaldehyde binder emulsions for nonwoven fabrics (column 1, lines 7-8), is non-analogous to that of the present invention, which relates to water-soluble or water-dispersible copolymers of hydroxyalkyl (meth)acrylates and their use in pharmaceutical dosage forms (specification page 1, lines 7-11). Applicants urge that one of ordinary skill in the art would not have looked to a reference such as Dragner et al. when seeking a water-soluble or water-dispersible coating agent, binder etc. for use in

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pharmaceutical dosage forms.

Therefore, Dragner et al. does not anticipate or render obvious the present claims.

Applicants would also like to point out that Goldberg et al. (US 3,203,918) does not disclose polymers where vinylic monomers are copolymerized in the presence of a polyvinyl alcohol. Goldberg et al. discloses linear random copolymers obtained by polymerizing vinylacetate, hydroxyalkyl acrylate and optionally crotonic acid monomers, in which after polymerization the acetate group is subsequently alcoholyzed to give a vinyl alcohol moiety (see column 2, lines 52-56). This is a different type of copolymer compared to the claimed copolymers.

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Respectfully submitted,

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